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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/723,248 | 11/25/2003 | Yves P. Arramon | PX-15 | 6049 |

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| EXAMINER | |
|---|---|
| CUMBERLEDGE, JERRY L | |
| ART UNIT | PAPER NUMBER |
| 3733 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/06/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/723,248 | ARRAMON, YVES P. | |
| | Examiner | Art Unit | |
| | Jerry Cumberledge | 3733 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3 and 6-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bischof et al. (US Pat. 4,915,688).

Bischof et al. disclose an implant material injection system comprising: a pressure driver (Fig. 1, ref. 42) (column 3, lines 58-64) and a separate container (Fig. 1 below) for implant material, wherein said driver and said separate container are adapted to form a sealed pressure-tight interface between each other; the pressure driver comprises a piston and a sleeve (column 3, lines 58-64), wherein said piston and said sleeve are adapted to draw implant material from the separate container into at least a portion of a chamber defined by said sleeve upon retracting said piston and to expel implant material from said pressure driver at a pressure level upon advancing the piston (column 3, lines 60-64) and a remote actuator connected to said pressure driver. Since the pressure driver comprises a syringe (column 3, lines 58-64), and the definition of a

syringe, according to the Merriam-Webster Online Dictionary is "an instrument (as for the injection of medicine or the withdrawal of bodily fluids) that consists of a hollow barrel fitted with a plunger and a hollow needle". The hollow barrel can be considered to be the hollow sleeve, and the plunger can be considered to be the piston. The remote actuator can be considered to be the proximal-most end of the plunger, which is furthest away from the main body of the device (Fig. 1, ref. 10). The definition of remote, according to the Merriam-Webster Online Dictionary, is "far removed in space, time or relation." The actuator of Bischof et al. is far removed relative to the main body of the device (*i.e.* Fig. 1, ref. 10), thus it can be considered to be a remote actuator.

The device of Bischof et al. is capable of performing a method of delivering flowable implant material, the method comprising: providing an implant material injection system comprising a pressure driver and container for implant material; connecting the pressure driver to cannula emplaced at a location for implant material delivery; loading the implant material into the pressure driver; driving material from the pressure driver into the implant material location; again loading implant material into the pressure driver and again driving material from the pressure driver into the implant material location.

Claims 25, 26, 32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Mazzuca et al. (US Pub. 2005/0070915 A1).

Mazzuca et al. disclose an implant material injection system adapted for performing a percutaneous vertebroplasty procedure comprising: a remote actuator (Fig. 2, ref. 40); a pump (Fig. 2, ref. 100) comprising a piston (Fig. 2, ref. 66) and a drive

chamber (Fig. 2, ref. 60), the pump having a distal end (Fig. 2, end near ref. 64) adapted to connect with a cannula (Fig. 2, ref. 30), the drive chamber adapted to hold implant material (paragraph 0054, lines 1-3) (paragraph 0056, lines 10-12), the piston adapted to drive the implant material through the distal end of the drive chamber to an implant site (paragraph 0057); a control line (Fig. 4, ref. 15) connecting the remote actuator and the pump (Fig. 4), the control line adapted to advance the piston (paragraph 0053, lines 7-9); and wherein the implant material comprises a flowable hard tissue implant material (paragraph 0054). The control line comprises a fluid column adapted to advance the piston (column 0053). The system further comprises a cannula (Fig. 2, ref. 30) removably connected with the distal end of the drive chamber. The implant material comprises polymethylmethacrylate (paragraph 0054).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3 and 6-16, 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bischof et al. (US Pat. 4,915,688) in view of Kline et al. (US Pat. 5,376,094).

Bischof et al. discloses the claimed invention except for the remote actuator comprising first and second grip portions; and a cable set within a housing connecting the actuator and the pressure driver.

Kline discloses the remote actuator comprising first and second grip portions (Fig. 3 below) in order to give the handle good fidelity and allow the operator to feel resistance that the end is feeling (column 1, lines 28-31); and a cable (or remote connection) (Fig. 3) set within a housing (Fig. 3) connecting the actuator and the pressure driver (Fig. 19 below), in order to move the piston and create a suction in the pressure driver and allow for withdrawal of fluid (column 6, lines 32-34).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the implant material injection system of Bischof et al. with the actuator having first and second grip portions, in order to give the handle good fidelity (column 1, lines 28-31); and a cable set within a housing connecting the actuator and the pressure driver, in order to move the piston and create a suction in the pressure driver and allow for withdrawal of fluid (column 6, lines 32-34).

The implant material injection system of Bischof as modified by Kline is capable of performing a method of delivering flowable implant material, the method comprising: providing an implant material injection system comprising a pressure driver and container for implant material; connecting the pressure driver to cannula emplaced at a location for implant material delivery; loading the implant material into the pressure driver; driving material from the pressure driver into the implant material location; again loading implant material into the pressure driver and again driving material from the

pressure driver into the implant material location. The implant material injection system of Bischof as modified by Kline is capable of performing a method including steps of withdrawing a first portion of the actuator relative to a second portion of the actuator to effect the loading and advancing the first portion toward the second portion to effect the driving. The device can perform the method at about 36 inches or greater from the location for implant material. The device includes a cable within a housing, which connects the remote actuator to the pressure driver. The device can perform a method in which the pressure level for driving the implant material reaches at least about 10 psi. The device can perform a method where the pressure level for driving the implant material does not exceed about 120 psi.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. The following claims have optimum or workable ranges:

With regard to claims 2 and 15 it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the implant material injection system of Bishof et al. as modified by Kline at a psi of 10 or greater.

With regard to claims 3 and 16 and, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the implant material injection system of Bishof et al. as modified by Kline at a psi of 120 or less.

With regard to claim 9, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the cable of Bischof et al. as modified by Kline about 36 inches in length or more.

With regard to claim 14, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the remote connection of Bischof et al. as modified by Kline about 36 inches in length or more.

It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). The following claim contains an optimum value of a result effective variable:

With regard to claim 9, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the cable of Bishof et al. as modified by Kline about 48 inches long.

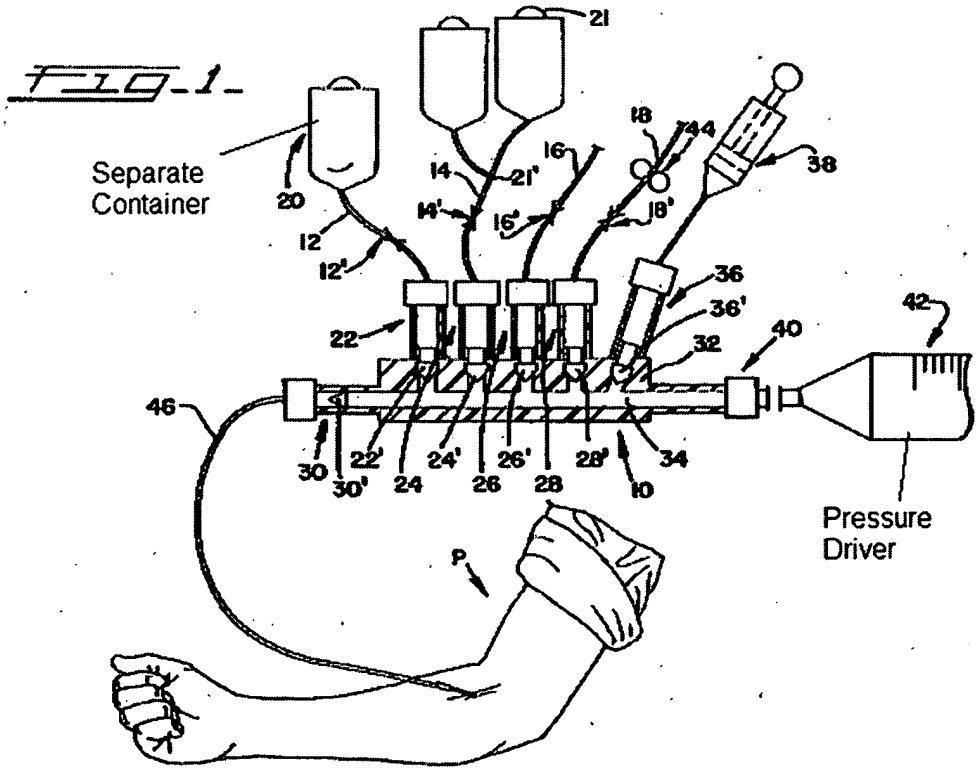
Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bischof et al. (US Pat. 4,915,688) in view of Peeler et al. (US Pat. 6,662,969).

Bischof et al. disclose the claimed invention except for the device further comprising a link connecting the remote actuator and the pressure driver, the link comprising a fluid column adapted to advance and retract the piston.

Peeler et al. disclose a device for hydraulically and volumetrically dispensing fluid (column 2, lines 51-52) with a remote actuator (column 3, lines 5-8) with a link comprising a fluid column (*i.e.* the hydraulic coupler containing incompressible hydraulic

fluid) adapted to advance and retract a piston (column 3, lines 12-18), this linking set-up being used to more accurately dispense a volumetric amount of fluid (column 3, lines 24-30).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the link of Bischof et al. with the link comprising a remote actuator comprising a fluid column adapted to advance and retract a piston as taught by Peeler et al., in order to more accurately dispense a volumetric amount of fluid (column 3, lines 24-30).



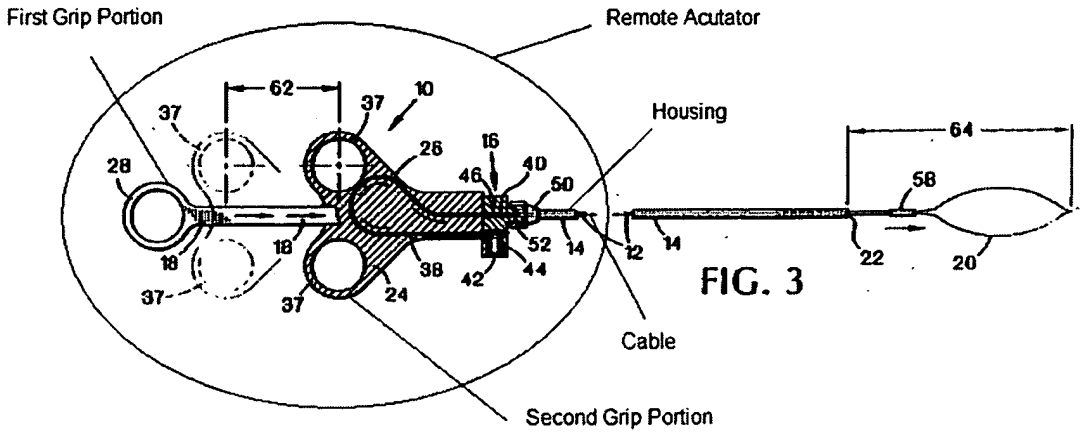

First Grip Portion
Remote Acutator
Housing
Cable
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FIG. 3

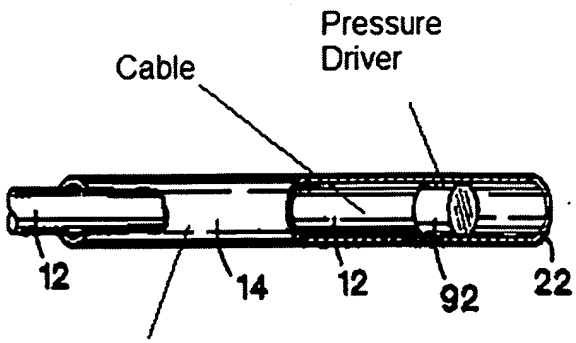


FIG. 19

Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzuca et al. (US Pub. 2005/0070915 A1).

With regards to claims 27, 28 and 30, Mazzuca et al. disclose the claimed invention except for the control line has a length of about one foot; the control line has a length of about 36 inches; the control line has a length of about 48 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the control line of Mazzuca et al. at a length of about one foot/ of about 36 inches/ of about 48 inches, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With regards to claims 29 and 31, Mazzuca et al. disclose the claimed invention except for the control line having a length of at least 36 inches; the control line having a length greater than 48 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the control line having a length of at least 36 inches/ the control line having a length greater than 48 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzuca et al. (US Pub. 2005/0070915 A1) in view of Bischof et al. (US Pat. 4,915,688) further in view of Lautenschlager et al. (US Pat. 5,902,839).

Mazzuca et al. disclose the claimed invention except for the system further comprising an implant material reservoir connected with the pump, the pump adapted to draw implant material from the material reservoir into the drive chamber.

Bischof et al. disclose a device comprising implant material reservoirs (Fig. 1, refs. 20 and 21) connected to a pump (column 3, lines 58-64), the pump being adapted to draw implant material from the material reservoir into the drive chamber (column 3, lines 58-64), the reservoirs being useful for holding supplies of different components and keeping them separate from the other components of a predetermined mixture (column 2, lines 54-57) until the time that they are required to be mixed and administered to a patient (column 2, lines 24-31).

Lautenschlager et al. disclose a bone cement (*i.e.* an implant material) that comprises at least two liquid components (column 2, lines 21-24), which can be held in separate containers in a single cement delivery device (column 3, lines 15-17) and mixed just prior to being delivered to the patient (column 2, lines 21, 24), the two separate liquid components being used in a delivery device having two separate storage components, in order to keep the components separate until they are required to be mixed (column 3, lines 15-19) after which they will harden (column 7, lines 24-26). An advantage of this system is that it introduces less air into the bone cement as it is being mixed (column 3, lines 15-23).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Mazzuca et al., which is used to deliver implant material (Mazzuca et al., paragraph 0054), with the implant material reservoirs of Bischof et al., in order to hold a bone cement (i.e. implant material) of Lautenschlager et al. The implant material reservoirs of Bischof et al. would provide the device of Mazzuca et al. with at least two separate containers to hold the separate components of the bone cement of Lautenschlager et al. This set-up would be advantageous because it would allow for less air to be introduced into the bone cement while it is being mixed (Lautenschlager, column 3, lines 15-23).

With regard to statements of intended use and other functional statements (e.g. "...are adapted to draw implant material..." and "...adapted to drive said piston..." and movement corresponds to 1 to 1 with movement..."), they do not impose any structural

limitations on the claims distinguishable over the device of Bischof et al. in view of Kline, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

***Response to Arguments***

In response to Applicant's argument that Bischof et al. do not disclose a system for injecting an implant material, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). Furthermore, the fact that Applicant uses the claimed invention for a different purpose does not alter the conclusion that its use in a prior art device would be prima facie obvious from the purpose disclosed in the reference. Applicant further argues that it is well known in the art that implant material (e.g. polymethylmethacrylate) has a much lower viscosity than the infusion fluids contemplated by Bischof and that the device taught by Bischof would not be suitable for injecting low viscosity fluids such as implant materials. With regards

to the viscosity of polymethylmethacrylate, it appears that this material would be more viscous than materials presented by Bischof et al., since polymethlymethacrylate is described as having a "dough-like" consistency (Wikipedia excerpt, page 2, paragraph beginning "In orthopedic..."), as opposed to the watery solutions presented by Bischof et al. Furthermore, Bischof et al. does not teach away from using more viscous materials. Indeed, Bischof et al. disclose, at least in one instance, that a more viscous material (*i.e.* "fat", column 2, lines 11-14) can be used with the device.

With regards to Applicant's argument that Bischof et al. do not disclose a remote actuation device, the examiner respectfully disagrees. The definition of remote, according to the Merriam-Webster Online Dictionary, is "far removed in space, time or relation." The actuator of Bischof et al. is far removed relative to the main body of the device (Bischof et al., Fig. 1, ref. 10), thus it can be considered to be a remote actuator.

With regards to Applicant's argument that non-return valve would '36 would prevent syringe 38 and its plunger from being "adapted to draw implant material from the separate container into at least a portion of a chamber", the examiner agrees. However, Fig. 2, ref. 42 does not contain such a valve (column 3, lines 56-57), and would be capable of drawing the implant material from the separate container into at least a portion of a chamber (column 3, lines 60-68).

With regards to Applicant's arguments that the device of Kline pertains to use with a snare device and does not provide any motivation for application with respect to the fluid delivery device of Bischof et al., the examiner respectfully disagrees. The specific embodiment of the Kline device used in the 103(a) rejection was an

embodiment of the Kline device that can be used as a syringe handle (Fig. 19 above) (column 6, lines 19-40). Greater fidelity is applicable to both the snare handle embodiments of the device and to the syringe handle embodiment of the device (*e.g.* greater fidelity for picking up small amounts of drugs, column 6, lines 21-23).

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER